

K021751

AUG 15 2002

## **Section 2**

### **510(k) Summary of Safety and Effectiveness**

## **1.0 Submitter Information**

- 1.1 Submitter: Hitachi Medical Systems America, Inc.  
1959 Summit Commerce Park  
Twinsburg, Ohio 44080-2371
- 1.2 Contact: Douglas J. Thistlethwaite  
Manager of Regulatory Affairs  
ph: (330) 425-1313  
fax: (330) 425-1410
- 1.3 Date: August 24, 2002

## **2.0 Device Name**

- 2.1 Classification Name: System, Nuclear Magnetic Resonance Imaging
- 2.2 Classification Number: 90LNH
- 2.3 Trade/Proprietary Name: ALTAIRE Magnetic Resonance Imaging System
- 2.4 Predicate Device(s): Hitachi Altaire MRI System (K002420)

## **3.0 Device Intended Use**

The MR system is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

## 4.0 Device Description

### 4.1 Function

The ALTAIRE is a Magnetic Resonance Imaging System that utilizes a 0.7 Tesla superconducting magnet in an open gantry design. The design was based on the AIRIS II Open MRI system. The ALTAIRE has been designed to enhance clinical utility by taking advantage of the imaging properties of the 0.7T magnet.

### 4.2 Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events. The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

### 4.3 Physical and Performance Characteristics

MRI is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. The biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In MR imaging, difference in proton density, blood flow, and T1 and T2 relaxation times can all contribute to image contrast. By varying the pulse sequence characteristics, the resulting images can emphasize T1, T2, proton density, or the molecular diffusion of water or other proton containing molecules.

## **5.0 Device Technological Characteristics**

The technological characteristics of this device are similar to the primary predicate device. The primary difference is the change of the RF transmit coil to allow it to operate in receive mode. The RF sub-system is also enhanced to support the transmit/receive function and to allow for future use of multiple array receive coils. The control and image processing hardware and the base elements of the operating system software are identical to the primary predicate device.

## **6.0 Conclusions**

It is the opinion of Hitachi Medical Corporation that ALTAIRE MRI system with the Transmit/Receive Coil feature is substantially equivalent to the listed predicate device. The intended use is identical to the listed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 15 2002

Mr. Doug Thistlewaite  
Manager, Regulatory Affairs  
Hitachi Medical Systems America, Inc.  
1959 Summit Commerce Park  
TWINSBURG OH 44087

Re: K021751

Trade/Device Name: Transmit/Receive Coil for Hitachi  
Altaire Magnetic Resonance Imaging  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance  
diagnostic device

Regulatory Class: II  
Product Code: 90 MOS  
Dated: May 24, 2002  
Received: May 28, 2002

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

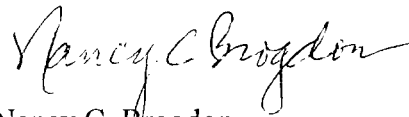
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021751

Device Name: Altaire Transmit/Receive Coil

**Indications for Use:**

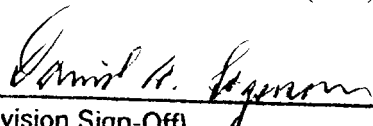
The Transmit/Receive Coil is a radial type, multiple element resonator coil used to obtain diagnostic images of the body when used with the Altaire MR Imaging system.

The Altaire MR Imaging system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MRI system produces axial, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. Among the NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Anatomical Region: Head, Body, Spine, Extremities  
Nucleus excited: Proton  
Diagnostic uses: T1, T2, proton density weighted imaging  
Diffusion weighted imaging  
MR Angiography  
Image processing

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K021751

Prescription Use ✓

OR

Over-the-Counter Use \_\_\_\_\_